

## REMARKS

Claims 13-15 are pending in the application and stand rejected. Claim 15 has been amended. Applicants respectfully request reconsideration and allowance of Claims 13-15.

### The Objection to the Specification

The Examiner has objected to the specification on the basis that the status of U.S. Application No. 09/326,500 as an issued patent has not been set forth. Applicants have amended the specification to indicate that this application has issued as U.S. Patent No. 6,348,610. Withdrawal of this ground of objection is respectfully requested.

### The Rejection of Claim 15 Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected Claim 15 under 35 U.S.C. § 112, second paragraph, as being indefinite for reciting "crossing sunflower seeds." Claim 15 has been amended to clarify that mutant sunflower lines are being crossed. Withdrawal of this ground of rejection is respectfully requested.

### The Rejection of Claims 13 and 14 Under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected Claims 13 and 14 under 35 U.S.C. § 112, first paragraph, as not being enabled by the specification. According to the Examiner, the mutant sunflower lines CAS-3 and IG-1297M are essential to the claimed invention, and although these two lines have been deposited under depository accession numbers ATCC-209591 and ATCC-75968, there is no indication in the specification as to public availability. The undersigned attorney of record affirms that the seeds of both deposited lines will be irrevocably and without restriction of condition released to the public upon the issuance of a patent.

### The Rejection of Claims 13 -15 Under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected Claims 13-15 under 35 U.S.C. § 112, first paragraph, as not being enabled by the specification on the basis that, even if the deposit requirement is met, the

claims are enabled only for sunflower seeds that are produced as a result of a cross between CAS-3 and IG-1297M, and having an oleic acid content of 47.2%, a linoleic acid content of 6.7%, a palmitic acid content of 30.5%, a stearic acid content of 9.6%, and 1.1% or less of other minor fatty acids. Applicants respectfully disagree.

Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of non-enablement of Claims 13-15. "When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement." *In re Wright*, 27 U.S.P.Q. 1510, 1513 (Fed. Cir. 1993); M.P.E.P. § 2164.04. For the reasons described below, applicants respectfully submit that the Examiner has not provided sufficient reasons for doubting that sunflower seeds containing oil having the recited fatty acid levels other than those of mutant line QQ-3598-M can be produced using the methods described in the specification. Therefore, the burden of establishing a *prima facie* case of non-enablement of Claims 13-15 has not been sustained.

As an initial matter, applicants' invention is directed to oil from seeds having a high palmitic acid content (more than 20% and less than 40%) while having a low content of palmitoleic acid and asclepic acid (less than 4%) (Specification, page 1, lines 12-14). Although sunflower lines containing oil with increased palmitic acid content have previously been obtained, the palmitoleic acid content in these lines was also increased to more than 4% (Specification, page 2, lines 14-18; page 4, lines 4-5; page 6, line 32 to page 7, line 2). Applicants have surprisingly found that it is possible to create sunflower lines containing oil with

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a high palmitic acid content and a low content of palmitoleic and asclepic acid by mutagenesis and selection.

The Examiner states that it is highly unpredictable that one of skill in the art would be able to practice the claimed invention without using the mutant lines IG-1297M and CAS-3 because (1) these two lines were produced by random and individual mutations; (2) there is a lack of working examples of plants producing seeds containing oils with fatty acid levels within the claimed ranges other than QQ-3598-M; and (3) there is absence of other methods of producing a sunflower seed having fatty acids that fall within the claimed ranges. In addition, the Examiner states that it is highly unpredictable for one of ordinary skill in the art to obtain seed having oil that has fatty acid levels falling within all six ranges. Based on these arguments, the Examiner concludes that it would require undue experimentation to practice the claimed invention. Applicants respectfully disagree for the following reasons.

*1. The Specification Describes Methods for Producing Other Mutant Lines like IG-1297M and CAS-3.*

The Examiner states that it is highly unpredictable that one of skill in the art would be able to practice the claimed invention without using the mutant lines IG-1297M and CAS-3 because these lines were produced by random and individual mutations. Applicants point out that the specification provides ample guidance for the mutagenesis of seeds and the analysis of mutagenized seeds to select for seeds containing oil with the desired fatty acid composition. Specifically, the specification describes three different methods for mutagenizing seeds-treatment of seeds with sodium azide, an alkylating agent, or x-rays (Specification, page 6, lines 16-24; page 7, lines 12-18, page 8, lines 2-6 and lines 15-17). In addition, the specification describes a method for analyzing the fatty acid composition of seeds (Specification, page 6, lines 10-13; page 7, lines 18-23; page 8, lines 6-9). Moreover, the specification describes three lines

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containing oils with an altered fatty composition that is stable, heritable and independent of growth conditions (Specification, page 6, lines 14-16). Therefore, the specification provides adequate guidance for one of ordinary skill in the art to produce other mutant lines containing oils with fatty acid contents similar to IG-1297M and CAS-3.

*2. The Specification Provides Adequate Working Examples For Producing Seeds Containing Oils within the Claimed Ranges.*

The Examiner also states that it is highly unpredictable that one of skill in the art would be able to practice the claimed invention without using the mutant lines IG-1297-M and CAS-3 based on the lack of working examples of plants producing seeds containing oils with fatty acid levels within the claimed ranges other than QQ-3598-M. The Examiner is reminded that "[t]he presence of only one working example should never be the sole reason for rejecting claims as being broader than the enabling disclosure, even though it is a factor to be considered along with all the other factors. To make a valid rejection, one must evaluate all the facts and evidence and state why one would not expect to be able to extrapolate that one example across the entire scope of the claims." M.P.E.P. § 2164.02. Moreover, the specification provides more than just one working example: the specification describes that crossing high stearic acid line CAS-3 with high palmitic acid line CAS-12 produces progeny in which the levels of palmitoleic and asclepic acid were decreased (Specification, page 7, lines 4-9). Therefore, the specification provides adequate working examples for producing seeds containing oils within the claimed ranges.

*3. One Disclosed Method for Producing The Claimed Seeds is Sufficient.*

The Examiner also states that it is highly unpredictable that one of skill in the art would be able to practice the claimed invention without using the mutant lines IG-1297-M and CAS-3 based on the absence of other methods of producing a sunflower seed having fatty acids that fall within the claimed ranges. Applicants respectfully point out that "[a]s long as the specification

discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied." M.P.E.P. § 2164.01(b). As noted above, the specification discloses more than one method for producing a sunflower seed containing oil having fatty acids that fall within the claimed ranges. Therefore, the methods disclosed in the specification bear a reasonable correlation to the scope of the claims and are sufficient to meet the enablement requirement.

*4. It is Not Unpredictable to Obtain Seed Having Oil With Fatty Acid Levels Within the Claimed Ranges.*

The Examiner also states that it is highly unpredictable that one of skill in the art would be able to obtain seed having oil that has fatty acid levels falling within all six ranges without using the mutant lines IG-1297-M and CAS-3. Applicants draw the Examiner's attention to the Table 1 and Examples 1 and 2 which describe prior art seeds containing oils with palmitic acid, stearic acid, oleic acid, and linoleic acid contents that are within the claimed ranges. Specifically, the specification describes seeds containing oils with a palmitic acid contents ranging from 5-31% (Specification page 3, Table 1), stearic acid contents ranging from 2-35% (Specification page 3, Table 1, page 7, line 12 to page 8, line 13), oleic acid contents ranging from 5-88% (Specification page 3, Table 1), and linoleic acid contents ranging from 2-68% (Specification page 3, Table 1). In fact, Table 1 discloses three lines containing oil in which each of these four fatty acids (i.e., palmitic acid, stearic acid, oleic acid, and linoleic acid) are within the claimed ranges. Thus, applicants are claiming seeds and methods for preparing seeds containing oil in which the levels of palmitic acid, stearic acid, oleic acid, and linoleic acid are kept within prior art ranges, but in which the levels of palmitoleic acid and asclepic acid are below 4%. As noted above, the specification describes methods for mutagenizing and selecting lines containing oils in which the levels of palmitoleic and asclepic acid are decreased while

maintaining high levels of palmitic acid. Therefore, applicants respectfully submit that it is not unpredictable that one of skill in the art would be able to obtain seed having oil that has fatty acid levels falling within the claimed ranges.

For all the reasons provided above, applicants submit that it would not require undue experimentation to practice the claimed invention. The fact that some experimentation is necessary does not preclude enablement. The Board of Patent Appeals and Interferences summarized this point well by stating:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed.

*Ex parte Jackson*, 217 U.S.P.Q. 804, 807 (Bd. Pat. App. Int. 1982). Applicants respectfully submit that the specification provides the requisite amount of guidance with respect to the direction in which the experimentation should proceed to enable one skilled in the art to determine how to practice the claimed invention. Moreover, methods for mutagenizing seeds and selecting seeds containing oil with desirable fatty acid contents represent routine technology to persons of ordinary skill in the art. Therefore, obtaining mutant lines other than those explicitly disclosed in the specification would require no more than routine experimentation in view of the teachings in the specification, the knowledge of one of ordinary skill in the art, and the level of skill in the art. Because the specification objectively enables sunflower seeds and methods for preparing sunflower seeds comprising an oil having the fatty acid content ranges recited in Claims 13-15, applicants respectfully request withdrawal of this ground of rejection.

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CONCLUSION

Applicants believe that the application is now in condition for allowance. If any issues remain that may be expeditiously addressed in a telephone interview, the Examiner is encouraged to telephone applicants' attorney at 206.695.1718

Respectfully submitted,

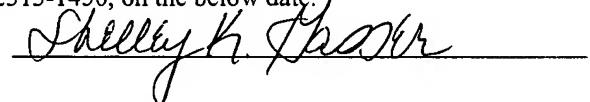
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Date: October 8, 2004



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